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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,421	12/14/2001	John E. Owens	5686.0046-00	3765

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Washington, DC 20005-3315

EXAMINER

CHRISTMAN, KATHLEEN M

ART UNIT	PAPER NUMBER
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3713

DATE MAILED: 08/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,421

Applicant(s)

OWENS ET AL.

Examiner

Kathleen M Christman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/30/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 20-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

In response to the amendment filed 04/30/2004, claims 1-19 and newly added claims 20-24 are pending.

Drawings

1. The drawings were received on 04/30/2004. These drawings are informal and do not fully overcome the previous drawing objections. The drawings are still missing descriptive legends for elements 12, 14, 22, and 38 in Figures 4 and 5. Additionally, elements 14 and 16 appear to both designate the piston. Further, the objection to Figures 1, 2, and 8 stands. These figures show modified forms of construction in the same view. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: In paragraph 39, the reference to Figure 6 appears to be improper. The examiner believes this should be a reference to Figure 8.

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Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-11 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang (US 5584701) in view of Bowden (US 6296490 B1). Lampotang teaches a simulated mechanical lung for system and a method of its use including: a reservoir having an outlet (the bellows); an actuator disposed in the reservoir for moving fluid in and out of the reservoir (the mass flow controller, col. 5: 34); and a control unit electrically coupled to the actuator for controlling the actuator to simulate the respiration pattern of a human (the computer and computing means, see Figures 5 and 6), as in claim 1. The reservoir having a pair of cylinders connected in parallel by a conduit (claim 2) is taught in at least, col. 16: 35-46, in the teaching of two bellows being used simulate a pair of lungs. The actuator including a piston (claim 3) is taught in col. 5: 42-44. A valve in fluid communication with the outlet of the reservoir, the valve being configured to control a flow rate of the fluid to and from the reservoir (claim 4) is taught in col. 17: 58-65. The control unit including a waveform generation device for generating a waveform defining the respiration pattern (claims 5 and 13), the control unit controlling the actuator based on the

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waveform to simulate the respiration pattern (claims 6 and 13) and the waveform generation device generating the waveform based on human respiratory characteristics (claims 7 and 14) are taught in col. 13: 8-15. The human respiratory characteristics being pre-stored in the control unit (claim 8 and 16) or that the characteristics may be inputted (claims 9 and 16) and the ability to modify the characteristics (claim 17) is taught in col. 14: 56-67, in that the basic patterns are stored and a user selects (or inputs) the desired options for the simulation. A pressure transducer in fluid communication with the reservoir and electrically coupled to the control unit (claim 10) and the control unit monitoring respiration pattern through the pressure transducer (claim 11 and 18) are taught in col. 17: 48-51.

Lampotang does not specifically teach the reservoir outlet leading to two passageways (claims 1 and 13). Bowden teaches a manikin including simulated lungs. The outlet of the simulated lung (Bowden's reservoirs) includes two passageways, one leading to the mouth of the manikin, the other leading to the nose, see Figure 1. It would have been obvious to one of ordinary skill in the art to modify the Lampotang et al training manikin with the passageways of the Bowden manikin so as to provide a realistic simulator (col. 4: 10-15 of Bowden).

4. Claims 12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang et al (US 5584701) in view of Bowden (US 6296490 B1) further in view of East, IV et al (US 5975748). Lampotang and Bowden teach all aspects of the invention as shown above, but fails to teach that the control unit including a data acquisition module to store the monitored respiration pattern (claim 12) or that the data is stored (method step of claim 19). East clearly shows this function in col. 4: 10-16. It would have been obvious to modify the system of Lampotang et al with the data acquisition abilities of East so as to allow a user to analysis the results of a simulation after the simulation has been completed, as taught by East.

Allowable Subject Matter

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5. Claims 20-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments, see the amendment, filed 04/30/2004, with respect to the rejection(s) of claim(s) 1-11 and 13-19 under 35 USC §102 have been fully considered. In view of applicant's amendment the previous rejection has been withdrawn, however, a new grounds of rejection based upon Lampotang in view of Bowden has been presented. Regarding the arguments that Lampotang does not teach a pair of cylinders connected in parallel to the conduit or an actuator that includes a piston disposed in the reservoir, the applicant has not shown how the components relied upon by the examiner do not teach these features. The arguments merely make the assertion that Lampotang does not teach such features. Regarding the assertion that Lampotang fails to teach a pressure transducer in fluid communication with reservoir and electrically coupled to the control unit to measure pressure, the applicant has failed to show how the sensor 101 is "not designed to measure pressure". Lampotang clearly teaches, "Once in the bellows gas pressure may be constantly assayed using pressure sensors". This teaching is enough to match the broad limitation of the claim.

In view of applicant's remarks the priority claim has been reconsidered. It is believed that the priority document does support the now pending claims.

The previous rejections under 35 USC §112, second paragraph have been overcome by the amendments made to the claims.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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- a. Kleinwaks et al (US 5403192) teaches a lung simulator for use in a mannequin


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

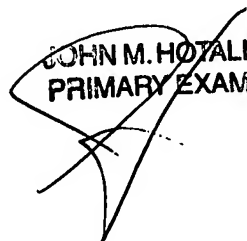
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Christman whose telephone number is (703) 308-6374. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks can be reached on (703) 308-1745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kathleen M. Christman


JOHN M. HOTALING, II
PRIMARY EXAMINER